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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,104	09/26/2003	Wan Ji	IVGN 354 CON	7870

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EXAMINER	
HORLICK, KENNETH R	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,104	JI ET AL.	
	Examiner	Art Unit	
	Kenneth R. Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71-96* is/are rejected.

7)☒ Claim(s) *91* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. This Office action is in response to the papers and petition filed 08/29/06.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. This objection is repeated from the prior Office action.

3. The specification is objected to because of the following informality: the continuation information must be updated to reflect issue of the parent '565 application as U.S. Patent No. 6,638,722. This objection is also repeated from the prior Office action.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY THE AMENDMENT

4. Claim 91 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This claim further adds a target nucleic acid, which is already required in amended claim 71. It is noted that claims 92-96 are dependent from claim 91.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 71-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohlander (US 5,731,171) in view of any one of Burgoyne (US 5,496,562, 5,756,126, or 5,972,386), or in view of Gerdes et al. (US 6,291,166).

These claims are drawn to a composition comprising: a target nucleic acid fixed to a solid medium, a first primer comprising a random sequence of nucleotides at its 3' end and a generic sequence 5' of the random nucleotides; a second primer comprising said generic sequence and lacking said random sequence; and a heat-stable DNA polymerase.

Bohlander discloses a kit comprising such a first and second primer along with such a polymerase (see columns 3-9 and 13-14, especially column 8, line 18 to column 9, line 24). This kit may be reasonably interpreted as a "composition" as claimed.

Bohlander does not disclose a target nucleic acid fixed to a solid medium.

Each of the Burgoyne patents discloses polymerase-mediated amplification of target nucleic acid fixed to a solid medium. In the '562 patent, see entire document, especially Example 3, wherein a blood sample stored on filter paper is treated and DNA therein is amplified by PCR. Although the patent does not use the terminology "fixed to a solid medium" to describe the target nucleic acid, one of ordinary skill in the art would recognize from textbook knowledge that the treatment of the DNA sample with Solution B in Example 3 would result in precipitation, and thus "fixing", of the DNA on the filter paper. In the '126 patent, see especially columns 3-7 and 9-17. In the '386 patent, see especially columns 2-7, 9-12, and 19-21.

Gerdes et al. disclose fixing DNA to solid phase media, and subjecting the fixed DNA to any of numerous applications, including repeated amplification strategies (see especially abstract, and column 3, line 32 to column 11, line 4). This method of Gerdes et al. provides numerous benefits/advantages/conveniences, as stated in column 3, lines 43-47: "[t]rue solid phase analysis provides for stringent aqueous washes, rapid automatable nucleic acid capture and purification, selective nucleic acid detection, repeat and/or expanded analysis of the bound nucleic acid, and long term storage of nucleic acid."

One of ordinary skill in the art would have been motivated to apply the amplification method and kit/composition of Bohlander to target nucleic acid fixed to a solid medium because both the Burgoyne and Gerdes et al. patents disclosed the advantages/convenience of using target nucleic acid fixed to a solid medium in methods of treating/manipulating/analyzing/amplifying nucleic acids. In other words, the skilled

artisan considering the combination of references would have recognized the nucleic acid-fixed solid medium of Burgoyne or Gerdes et al. to be an obvious application for use in the amplification method/kit/composition of Bohlander. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed compositions. As far as dependent claim limitations not specifically addressed above, these relate merely to additional conventional polymerases, labels, primer sites, and target nucleic acids. As these represent mere textbook knowledge or routine optimization, one of ordinary skill in the art would have been motivated to use them for their well known and obvious benefits.

6. Claims 71-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Zheleznaya et al. or Grothues et al., in view of Bohlander (US 5,731,171), and further in view of any one of Burgoyne (US 5,496,562, 5,756,126, or 5,972,386), or further in view of Gerdes et al. (US 6,291,166).

The subject matter of these claims, as well as the teachings of Bohlander, Burgoyne, and Gerdes et al., are discussed above.

Zheleznaya et al. teach a method which utilizes: a first primer comprising a random sequence of nucleotides at its 3' end and a generic sequence 5' of the random nucleotides; a second primer comprising said generic sequence and lacking said random sequence; and a heat-stable DNA polymerase (see pages 373-377).

Grothues et al. teach a method which utilizes: a first primer comprising a random sequence of nucleotides at its 3' end and a generic sequence 5' of the random

nucleotides; a second primer comprising said generic sequence and lacking said random sequence; and a heat-stable DNA polymerase (see pages 1321-1322).

Neither Zheleznaya et al. nor Grothues et al. disclose the claimed composition.

Kits or compositions combining reagents for facilitating the practice of methods requiring such reagents were conventional in the art at the time of the invention. This is supported by Bohlander, which as discussed above discloses kits.

One of ordinary skill in the art would have been motivated to combine the first and second primers and heat-stable polymerase of Zheleznaya et al. or Grothues et al. into a composition or kit because this would have clearly been useful in carrying out the method of Zheleznaya et al. or Grothues et al. The skilled artisan would have been further motivated to include a target nucleic acid fixed to a solid medium in such a composition or kit based on the teachings of Burgoyne or Gerdes et al., as discussed above. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed compositions.

7. No claims are free of the prior art.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kenneth R. Horlick, Ph. D.
Kenneth R Horlick
Primary Examiner
Art Unit 1637

11/21/06